



Cytori Therapeutics, Inc.  
Kenneth Kleinhenz  
Sr. Director, RA  
3020 Callan Road  
San Diego, California 92121-1109

June 8, 2021

Re: K063235

Trade/Device Name: Cytori Lipoplasty System With Celase Reagent  
Regulation Number: 21 CFR 878.5040  
Regulation Name: Suction lipoplasty system  
Regulatory Class: Class II  
Product Code: QPB

Dear Kenneth Kleinhenz:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated January 24, 2007. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Cindy Chowdhury, OHT4: Office of Surgical and Infection Control Devices, 240-402-6647, [Cindy.Chowdhury@fda.hhs.gov](mailto:Cindy.Chowdhury@fda.hhs.gov).

Sincerely,

Cindy Chowdhury -S

Cindy Chowdhury, Ph.D., M.B.A.  
Assistant Director  
DHT4B: Division of Infection Control  
and Plastic Surgery Devices  
OHT4: Office of Surgical  
and Infection Control Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Cytori Therapeutics, Inc.  
% Mr. Kenneth K. Kleinhenz  
Sr. Director of Regulatory Affairs  
3020 Callan Road  
San Diego, California 92121

JAN 24 2007

Re: K063235

Trade/Device Name: Cytori Lipoplasty System with Celase Reagent  
Regulation Number: 21 CFR 878.5040  
Regulation Name: Suction lipoplasty system  
Regulatory Class: II  
Product Code: MUU  
Dated: January 5, 2007  
Received: January 9, 2007

Dear Mr. Kleinhenz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

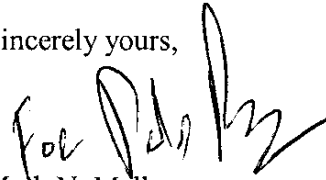
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Kenneth K. Kleinhenz

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "for [unclear] Melkerson". The signature is stylized and written over the printed name.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K063235  
**Indications for Use**

Device Name: Cytori Lipoplasty System with Celase Reagent

**Indications for Use:**

The Cytori Lipoplasty System is intended for use in the following surgical specialties when the fragmentation, emulsification, and aspiration of soft tissue is desired:

- Neurosurgery
- Gastrointestinal and Affiliated Organ Surgery
- Urological Surgery
- Plastic and Reconstructive Surgery
- General Surgery
- Orthopedic Surgery
- Gynecological Surgery
- Thoracic Surgery
- Laparoscopic Surgery

The Cytori Lipoplasty System is indicated for use when the fragmentation, emulsification, and aspiration of subcutaneous fatty tissues for aesthetic body contouring is desired.

The Celase Reagent is intended for use in the fragmentation, emulsification, disaggregation, and liquefaction of soft tissues and subcutaneous fatty tissues within the Lipoplasty System's collection canister.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number

K063235

**ADMINISTRATIVE INFORMATION**

Manufacturer Name: Cytori Therapeutics, Inc.  
3020 Callan Road  
San Diego, CA 92121

Official Contact: Kenneth K. Kleinhenz  
Sr. Director of Regulatory Affairs  
Telephone (858) 458-0900  
Fax (858) 458-0994

JAN 24 2007

**DEVICE NAME**

Classification Name: Suction Lipoplasty System  
Trade/Proprietary Name: Cytori Lipoplasty System  
with Celase Reagent

**ESTABLISHMENT REGISTRATION NUMBER**

2031733

**DEVICE CLASSIFICATION AND PRODUCT CODE**

As shown in 21 CFR 878.5040, Suction Lipoplasty Systems are defined as devices consisting of collection bottles, cannulas, and connecting tubing for use in aesthetic body contouring procedures. Suction Lipoplasty Systems are classified as Class II. They have been assigned Product Code MUU.

**INTENDED USE**

The Cytori Lipoplasty System is intended for use in the following surgical specialties when the fragmentation, emulsification, and aspiration of soft tissue is desired:

- Neurosurgery
- Gastrointestinal and Affiliated Organ Surgery
- Urological Surgery
- Plastic and Reconstructive Surgery
- General Surgery
- Orthopedic Surgery
- Gynecological Surgery
- Thoracic Surgery
- Laparoscopic Surgery

The Cytori Lipoplasty System is indicated for use when the fragmentation, emulsification, and aspiration of subcutaneous fatty tissues for aesthetic body contouring is desired.

The Celase Reagent is intended for use in the fragmentation, emulsification, disaggregation, and liquefaction of soft tissues and subcutaneous fatty tissues within the Lipoplasty System's Collection Canister.

## DEVICE DESCRIPTION

### Design Characteristics

The Cytori Lipoplasty System with Celase Reagent is provided in two packaged assemblies: 1). Lipoplasty Unit 2). Celase Reagent. The Lipoplasty Unit is a single-use disposable device designed to utilize house vacuum to create suction within the hollow liposuction cannula and remove subcutaneous fatty tissue from the patient and transport the adipose tissue into the collection canister. The Celase Reagent is a single-use, non-reusable reagent designed to digest the waste tissue in the collection canister as a means to allow the tissues to efficiently flow through the filter screen and mitigate down-stream clogging and blockage in the waste system.

### *Lipoplasty Unit*

The Cytori Lipoplasty System is a sterile, single-use, manual device consisting of a cannula, connection tubing and a waste collection container that relies on house vacuum for its energy supply. The pre-assembled Lipoaspirate Unit **alleviates assembly errors at the point of care and prevents the misuse of incompatible parts.** The cannula handle is attached to the collection canister via connection tubing. The cannula is a hollow tube with a single opening near the tip to communicate house vacuum to the tissues and subsequently fragment, emulsify, and aspirate subcutaneous fatty tissues from the patient into the waste collection canister for purposes of aesthetic body contouring. The tip is fabricated from medical grade stainless steel and the handle is fabricated from medical grade polypropylene. The connection tubing is fabricated from medical grade polyvinyl chloride (PVC) that is DEHP free. The waste collection container is fabricated from medical grade polycarbonate **to assure robustness in the operating room environment.** The collection canister contains various capped/sealed reagent ports and a 1190 micron filter to trap large tissue masses while allowing liquified tissue to pass through to a hospital-provided collection trap. This mechanism prevents large tissue masses from accumulating and subsequently clogging down-stream tubing that could interfere with vacuum.

The Lipoplasty cannula is provided in various sizes ranging from 15cm – 36cm in length and 3.0 – 4.6mm in diameter with a single opening near the tip of the cannula. The tip region of the cannula may have a single or multiple openings that range in size from 4mm to 12mm in length distributed uniformly or randomly throughout the end of the cannula. The handle of the device is 20mm in diameter and may be provided in diameters ranging from 20mm to 60mm in diameter. The connecting tubing is provided with an inner diameter of 9.6mm (3/8”), an outer diameter of 14.3mm (9/16”), and a wall thickness of 2.2mm. The tubing that connects the cannula handle to the waste canister is provided in a length of 4 feet and may be provided in lengths ranging from 1 – 8 feet. The bottom of the waste collection container is also provided with the same 3/8” inner diameter connection tubing of various lengths. The proximal end of the exiting connection tubing may be provided with a barbed tubing connector to assist in the attachment of like-sized tubing for purposes of connecting the Cytori Lipoplasty System to house vacuum and/or assorted waste traps. Connection tubing leading to and from the waste collection container is provided with a stepped clamp to facilitate manual control of the vacuum supplied to the cannula. The stepped clamps also allow the operator to seal the connection tubing on both sides of the collection canister and prevent spillage of the collected fluids/tissues, thereby facilitating safe transport and disposal of the waste materials.

### *Celase Reagent*

The Celase Reagent is a mixture of proteolytic enzymes provided in 70mg lyophilized powder form packaged in a single-use unit consisting of an amber vial with a rubber stopper and associated screw-top cap within a foam-protected aluminum canister.

**Material Composition**

The components of the Cytori Lipoplasty System that have patient contact are fabricated from surgical stainless steel. The Celase Reagent is a lyophilized blend of buffered salts and proteolytic enzymes

**Sterility**

The Cytori Lipoplasty System is sterilized by ethylene oxide (EtO) gas. The Celase Reagent is processed aseptically and sterile filtered.

**In Vitro Testing**

Mechanical testing of the Cytori Lipoplasty System with Celase Reagent demonstrates that the device is substantially equivalent to the predicate.

**EQUIVALENCE TO MARKETING PRODUCT**

The Cytori Lipoplasty System with Celase Reagent shares indications and design principles with the following predicate device which has been determined by FDA to be substantially equivalent to a pre-amendment device: MacroPore Lipoplasty System (K042261), Flow Laboratories Trypsin (K771955) and Oxoid USA Sputasol (K802493); Class II medical devices that were cleared for marketing in the United States under K042261, K771955, and K802493 respectively.

**Indications For Use**

The Cytori Lipoplasty System with Celase Reagent and the MacroPore Lipoplasty System predicate device share substantially equivalent indications for use as they are both indicated for the fragmentation, emulsification and aspiration of soft tissues in aesthetic body contouring procedures and are indicated for the same surgical specialties. The Cytori Lipoplasty System with Celase Reagent shares indications for use language with the predicate devices.

**Design and Materials**

The design and materials of Cytori Lipoplasty System with Celase Reagent and the predicate device (MacroPore Lipoplasty System) are substantially equivalent as they both utilize a hollow tubular cannulas attached to a handle. The cannula tip of the subject device and the predicate devices contains one or several openings to allow communication between the applied vacuum and the patient's tissues. The Cytori Lipoplasty System with Celase Reagent and the MacroPore Puricel Lipoplasty System predicate device are substantially equivalent in design as they both consist of a cannula, connection tubing, and a waste collection container. The waste collection containers on the Cytori Lipoplasty System with Celase Reagent and the MacroPore Puricel Lipoplasty System predicate device are provided in substantially equivalent volume capacities. The Cytori Lipoplasty System with Celase Reagent and the predicate devices (Trypsin and Sputasol Reagents) are substantially equivalent as they all enzymatically digest tissues and cells in vitro.